OCT 1 9 2001

K012320

July 20, 2001

SUMMARY OF SAFETY AND EFFECTIVENESS

In accordance with the requirements of the Safe Medical Device Act of 1990 and 21 CFR 807.92, Linvatec Corporation is hereby submitting the 510(k) Summary of Safety and Effectiveness for the PowerPro™ Battery System, 510(k) Number _____.

A. Submitter

Linvatec Corporation
11311 Concept Boulevard
Largo, Florida 33773-4908

B. Company Contact

Laura D. Seneff, RAC
Manager, Regulatory Affairs
(727) 399-5234 Telephone
(727) 399-5264 FAX

C. Device Name

Trade Name: PowerPro™ Battery System

Common Name: Battery powered surgical instrument and accessories/attachments

Classification Names:
Surgical instrument motors and accessories/attachments 878.4820
Sterilization Wrap 880.6850

Proposed Class/Device: II
Product Code HAB, FRG

K012320

D. Predicate/Legally Marketed Devices

PowerPro™ Electric System, Linvatec Corporation
Advantage™ System, Linvatec Corporation
Synthes® Power Drive System, Synthes
Allegiance Genesis™ Container System, Allegiance Healthcare Corp.

E. Device Description

The PowerPro Battery System is a powered instrument system consisting of various pistol-grip handpieces, universal battery charger, rechargeable batteries and sterilization trays. The handpieces utilize various attachments, such as blades, burs, drills and routers.

F. Intended Use

The PowerPro™ Battery System functions as a powered instrument system consisting of handpieces and accessories to perform cutting of soft tissue and bone. The fields of application include orthopedic procedures such as osteotomies, small and large bone trauma, orthopedic reconstruction, and total joint replacement, neurosurgical fusion and plating procedures, and medial sternotomy.

The PowerPro Battery System also includes a sterilization case to enclose the rechargeable batteries during sterilization, and also to maintain sterility of the batteries until used.

G. Substantial Equivalence

The PowerPro Battery System is substantially equivalent in design, function and intended use to the predicate devices named above. The PowerPro Battery System does not raise any new safety or effectiveness issues when compared to these similar devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 1 9 2001

Ms. Laura D. Seneff, RAC
Manager, Regulatory Affairs
Linvatec Corporation
11311 Concept Boulevard
Largo, Florida 33773

Re: K012320
Trade/Device Name: PowerPro™ Battery System
Regulation Number: 878.4820, 880.6850, 882.4360
Regulation Name: Surgical instrument motors and accessories/attachments
Sterilization wrap
Electric cranial drill motor
Regulatory Class: II
Product Code: GEY, FRG, HBC
Dated: July 20, 2001
Received: July 23, 2001

Dear Ms. Seneff:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Susan Walker, MS

for

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

July 20, 2001

510(k) Number (if known): K012320

Device Name: PowerPro™ Battery System

Indications for Use:

The PowerPro™ Battery System functions as a powered instrument system consisting of handpieces and accessories to perform cutting of soft tissue and bone. The fields of application include orthopedic procedures such as osteotomies, small and large bone trauma, orthopedic reconstruction, and total joint replacement, neurosurgical fusion and plating procedures, and medial sternotomy.

The PowerPro Battery System also includes a sterilization case to enclose the rechargeable batteries during sterilization, and also to maintain sterility of the batteries until used.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE If NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-Counter Use ___
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K012320